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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION N
09/879,911	06/14/2001	Max Aebi	8932-471	7179

7590 10/01/2004  
PENNIE & EDMONDS LLP  
1667 K Street, N.W.  
Washington, DC 20006

EXAMINER

REIP, DAVID OWEN

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/879,911

Applicant(s)

AEBI ET AL.

Examiner

David O. Reip

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 5,7-16,19,23-25 and 27-29 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26 and 30-32 is/are allowed.
- 6) ☒ Claim(s) 1-4,6,17,18,20-22 and 33-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election without traverse of Species 5 in the reply filed on 9/07/04 is acknowledged.

Claims 5, 7-16, 19, 23-25, and 27-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/07/04.

### *Response to Amendment*

The amendment filed 9/29/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: New figure 8A and all amendments to the specification to support new figure 8A. Clearly, since the applicant found it necessary to add extensive amendments to the specification in order to provide an adequate written description of an alternative "double blade" embodiment of the embodiment of the removable blade distractor of Fig. 1, such amendments are prima facie evidence that the disclosure as originally filed did not provide adequate written description for an embodiment as shown in newly proposed Fig. 8A.

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Drawings***

The drawings are objected to because:

Regarding Fig. 14, the character reference numbers "214" and "212" have not been applied in accordance with the specification. Specifically, the blades should be indicated as --244-- and the jaws should be indicated as --214--;

Regarding Fig. 16, the spaced apart distance between the blades is indicated as "T." However, page 11, line 15 of the specification refers to a distance D.

Regarding any of Figs. 14-16, no thickness T has been indicated, as per page 11, lines 20 and 33 of the specification.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled

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"Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4, 6, 17, 18, 20, 21, and 33-35 are rejected under 35 U.S.C. 101

because the claimed invention is directed to non-statutory subject matter. With respect to claim 1, lines 13-14, "wherein said first and second sets of blades *contact* (emphasis added) anatomical elements to be distracted" is a positive recitation of anatomical elements, such anatomical elements being portions of bone or other body tissue.

Suggest amending the claim language to "wherein said first and second sets of blades are adapted to contact anatomical elements to be distracted" or "wherein said first and second sets of blades are configured to contact anatomical elements to be distracted."

Then Assistant Secretary and Commissioner of Patents and Trademarks, Donald J. Quigg, issued a notice in the Official Gazette stating, "A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution." 1077 OG 24 (1987), reprinted in 1146 TMOG 24 (1993).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4, 6, 17, 18, 20-22, and 33-35 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Ray (WO 98/34552). Figs. 6, 7, and 8B of Ray show a distractor device having all the limitations as recited in the above listed claims, including: first and second handles 25; first and second jaws 22, the jaws including at least one curved portion (see area of 33 in Fig. 8B); first and second sets of spaced, integrally attached blades 32, the tips of the blades being curved, thus “including at least one curved portion” (see Fig. 8B); and a distractor mechanism 26-29.

Under the law of anticipation, it is necessary only that the claim in question “read on” the reference. As to functions recited, it is necessary only that the prior art be “capable of” performing the intended function. That being the case, the above listed claims read on Ray and are therefore anticipated. The blades 32 of Ray are fully capable of being inserted between adjacent vertebrae in direct contact with the vertebral bodies (“anatomical elements”). Further, the blades of Ray are separated by a dimension sufficient to permit insertion of an implant, i.e. blades 32 are separated by at least the same dimension as the dimension between channels 14 of the fusion cage 10, and therefore are separated enough to permit insertion of the central core preform 27 (an implant) therebetween without the implant contacting the blades.

With respect to method claim 22, applicants have previously argued that Ray does not disclose, teach, or suggest positioning the first and second sets of blades against spaced apart ends of first and second vertebral endplates, respectively. However, the positioning steps as broadly recited do not preclude intervening elements between the blades and the vertebral endplates, such intervening elements in Ray being the lateral stabilizer channels 14. Stated plainly, the method disclosed by Ray includes the tips 32 abutting channels 14 on one side and the channels 14 abutting the vertebral endplates on the other side. Such an arrangement meets the recited "positioning" limitations and therefore Ray anticipates the claim.

***Allowable Subject Matter***

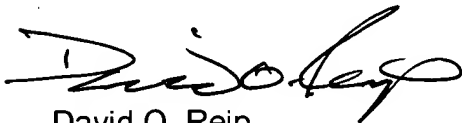
Claims 26 and 30-32 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David O. Reip whose telephone number is 703-308-3383. The examiner can normally be reached on 7 A.M.- 4 P.M. Mon-Thu and every other Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 703-308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "David O. Reip", written in a cursive style.

David O. Reip  
Primary Examiner  
AU 3731